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www.sleepapnea.org



April 27, 2001

Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW
Washington, DC 20580

Re: File No. 002-3210, In the Matter of Tru-Vantage International, LLC.
And
File No. 002 3211, In the Matter of Med Gen, Inc. and Paul B. Kravitz

Dear Secretary:

We have read the above-mentioned complaints and agreements and commend the Federal Trade Commission for taking action against the above-named companies and individual. The American Sleep Apnea Association agrees with the FTC that misleading claims about products can harm the health of Americans. The consent order, once implemented, will allow the public to evaluate better the product being considered for purchase and will help educate the public about a common but rarely diagnosed medical disorder.

The ASAA would like to suggest two minor changes to Section II of both agreements. Section II notes that the respondents will advise that "persons who have symptoms of sleep apnea should consult a physician." We ask that the wording be modified slightly to say that "persons who have symptoms of sleep apnea should consult a physician or a sleep specialist." The reason for this is simply that many physicians have not been educated about sleep apnea. In fact, in 1990 the Congressional Commission on Sleep Disorders Research sponsored a study of all medical schools in the US and found that the "average number of hours of preclinical sleep-related medical school content is 1.16 hours per school." Patients whose doctor is not familiar with sleep disorders should know that if they cannot get a satisfactory answer from their own doctor about their sleep problems, they can also contact a sleep specialist. As you can see from the enclosed print public service announcement from the National Center for Sleep Disorders Research, the National Institutes of Health uses similar language: "See your doctor or a sleep specialist."

We suggest further that in describing the symptoms of sleep apnea, the FTC ask the respondents to avoid the term "excessive daytime sleepiness" and instead use the language "falling asleep easily and/or sometimes inappropriately." "Excessive daytime sleepiness" is a medical term that is not well understood by the general public, yet the

The ASAA is a non-profit organization dedicated to reducing injury, disability, and death from sleep apnea and to enhancing the well-being of those affected by this common disorder.



average person knows if he/she falls asleep quickly at night or while reading, watching television, or sitting in meetings.

We would also encourage MedGen to include in its product inserts and/or on the outside packaging information about the American Sleep Apnea Association next to the information about symptoms of sleep apnea. The manufacturer of Breathe-Right nasal strips, an anti-snoring product, has done this for approximately two years now. The instructions (a copy of which is enclosed) include the line in the section about sleep apnea, "For more information, contact the American Sleep Apnea Association at 202/293-3650." Further, in a recent mass mailing, CNS, after working with us on the language, revised its warning on sleep apnea to say: "If you are told that you sometimes stop breathing during sleep, or if you fall asleep easily or inappropriately, you may have Sleep Apnea. This can be a serious medical condition that requires accurate diagnosis and proper treatment. If you suspect you have this condition, please consult your doctor or a sleep specialist. For more information, contact the American Sleep Apnea Association at 1-202-293-3650 or visit their website at www.sleepapnea.org." (A copy of this warning is also enclosed.) In addition, CNS has a link from its website on Breathe-Right to our website. We believe CNS is performing an important public service by listing the ASAA contact information: we regularly receive calls from people who purchased Breathe-Right nasal strips and who have never before known where to learn more about their symptoms. We would be happy to work also with MedGen about appropriate language for its product packaging.

Please do not hesitate to contact us if we can be of further assistance, and thank you again for your efforts on behalf of people with unrecognized sleep apnea.

Sincerely,

A handwritten signature in cursive script, appearing to read "M. Safwan Badr".

M. Safwan Badr, MD
President

We're up 200 times a night. Only he doesn't remember.

Every night my husband snores loudly. But it's those periods of silence in between the snoring, when he's stopped breathing, that really have me sleepless. I worry he may never take another breath. Then suddenly, he gasps for air. He doesn't realize it, but this goes on repeatedly throughout the night. By morning, we both feel like we haven't slept a wink.

If this sounds familiar, your spouse may be one of the 12 million Americans who have sleep apnea. It not only robs you of a good night's sleep, it can be life threatening. So don't take chances. See your doctor or a sleep specialist.

SLEEP APNEA.

It's no way to sleep. It's no way to live.

NATIONAL CENTER ON SLEEP DISORDERS RESEARCH | NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
National Institutes of Health | Public Health Service | U.S. Department of Health and Human Services

**It wasn't his
snoring that
kept me up
all night.
It was the
silence in
between.**

If your spouse snores loudly and periodically stops breathing throughout the night, it could be something serious. Your spouse may be one of the 12 million Americans who have a life-threatening sleep disorder called sleep apnea. See your doctor or a sleep specialist. That way, you both can get some rest.

SLEEP APNEA.

It's no way to sleep. It's no way to live.

NATIONAL CENTER ON SLEEP DISORDERS RESEARCH
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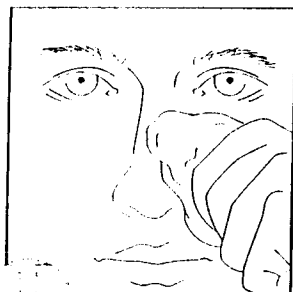
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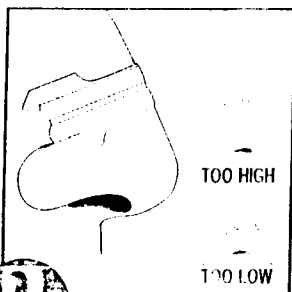
NATIONAL CENTER ON SLEEP DISORDERS
RESEARCH | NATIONAL HEART, LUNG,
AND BLOOD INSTITUTE
National Institutes of Health
Public Health Service
U.S. Department of Health and Human Services

INSTRUCTIONS

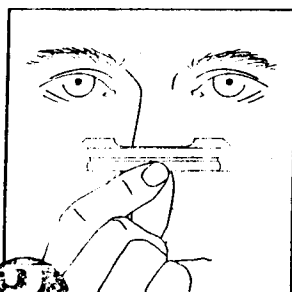
Breathe Right
nasal strips



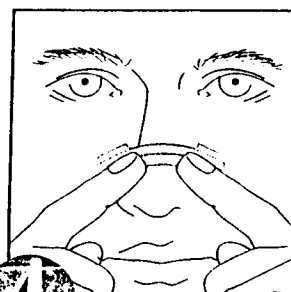
1 Wash and dry your nose thoroughly.



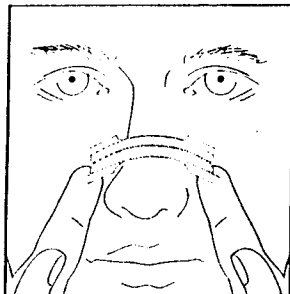
2 Place strip correctly for best results.



3 To apply, remove protective liner and center the strip on your nose.



4 Gently rub down from center to secure.



Remove SLOWLY.

Do this while washing your face or showering with warm water.

Loosen the tabs at the ends, then gently lift both sides.

FOR SINGLE USE ONLY

Helpful Hints

- **Size is important:** Choose carefully. Get the right size for maximum benefit.
Sm/Med – for an adult with a small to average size nose or for an adolescent.
Med/Lg – for an adult with a larger nose.
- Do not touch the adhesive at the ends of the strip.
- Oily skin? Use an astringent to clean the surface of your nose first.
- If your skin is dry after removing the strip, try using a skin moisturizer.
- If you have sensitive skin, try using a drop of lotion under the center part of the strip. It's alright if the lotion interferes with the adhesive; only the ends of the strip need to adhere for it to work.
- For exercise and athletics: Apply the strip about 30 minutes before you begin – this will improve adhesion when you perspire. If the strip loosens due to perspiration, use an astringent to clean the surface of your nose before applying.

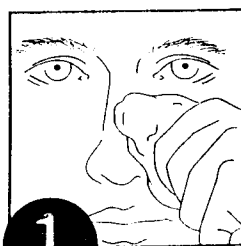
CAUTIONS: For external use only. Do not use over sores, sunburned, or irritated skin. Do not use for more than 12 hours per day. Disposable; use each strip only once. If rash or skin irritation occurs, discontinue use. Not for children under 5 years of age. Packaging of this product contains natural rubber latex which may cause allergic reactions.

COMMENTS? Please call us toll-free at 1-800/858-NOSE (6673) or write us at Breathe Right nasal strips, P.O. Box 39802, Minneapolis, MN 55439. Visit our website at www.breatheright.com.

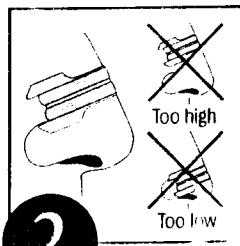
SLEEP APNEA. If you are told that you sometimes stop breathing during sleep, or if you experience excessive daytime sleepiness or fall asleep at inappropriate times, you may have Sleep Apnea. This can cause a serious medical condition requiring accurate diagnosis and proper treatment. If you suspect you have this condition, please consult your doctor. For more information, contact the American Sleep Apnea Association at 1-202-293-3650.

Correct placement is important for maximum results:

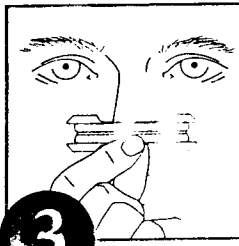
**Try
the free sample
right now.**



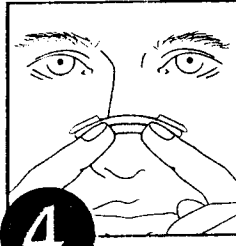
1
Wash and dry your nose thoroughly.



2
Place strip as pictured for best results.



3
To apply, remove the protective liner and center strip on your nose.



4
Gently rub down from center to secure.



To Remove:

Remove slowly. Do this while washing your face or showering with warm water. Loosen the tabs at the ends, then gently lift both sides.

Helpful Hints

- Do not touch the adhesive at the ends of the strip.
- Oily skin? Use an astringent to clean the surface of your nose first.
- If your skin is dry after removing the strip, try using a skin moisturizer.
- If you have sensitive skin, try using a drop of lotion under the center part of the strip. It's all right if the lotion interferes with the adhesive; only the ends of the strip need to adhere for it to work.
- For exercise and athletics: Apply the strip about 30 minutes before you begin - this will improve adhesion when you perspire. If the strip loosens due to perspiration, use an astringent to clean the surface of your nose before applying.

FOR SINGLE USE ONLY

Size is important. Breathe Right strips come in **Small/Medium** for adults with a small to average size nose and **Large** for adults with a larger nose. Either size will work, but one will fit more comfortably and do the job better. We've included three samples of each size for you to try.

CAUTIONS: For external use only. Do not use over sores, sunburned or irritated skin. Disposable, use each strip only once. Do not use for more than 12 hours per day. If rash or skin irritation occurs, discontinue use. Not for children under 5 years of age. Packaging of this product contains natural rubber latex which may cause allergic reactions. **INDICATIONS:** Breathe Right® nasal strips can provide temporary relief from nasal congestion and stuffiness and may also reduce or eliminate snoring. Use while sleeping, exercising, or during the day.

COMMENTS? Please call us toll-free at 1-800/858-NOSE (6673) or write us at Breathe Right nasal strips, P.O. Box 1985, South Hackensack, NJ 07606-9867. Visit our website at www.breatheright.com.

SLEEP APNEA. If you are told that you sometimes stop breathing during sleep, or if you fall asleep easily or inappropriately, you may have Sleep Apnea. This can be a serious medical condition that requires accurate diagnosis and proper treatment. If you suspect you have this condition, please consult your doctor or a sleep specialist. For more information, contact the American Sleep Apnea Association at 1-202-293-3650 or visit their website at www.sleepapnea.org.

This mailing is intended to provide current information on snoring. It is not intended by the authors or CNS, Inc. to be used for self-diagnosis or to suggest only one specific treatment. Please consult a physician for diagnostic or therapeutic recommendations tailored to your needs. Information provided by Meir Kryger, M.D., Martin Scharf, Ph. D., Kingman Strohl, M.D., and Daniel E. Cohen, M.D.

© 2001 CNS, Inc. Breathe Right nasal strips improve nasal breathing by reducing airflow resistance. "Breathe Right" and "CNS" are registered trademarks and "Breathe Right. Right Now" is a trademark of CNS, Inc. Breathe Right nasal strips are manufactured by CNS, Inc., Minneapolis, MN 55439. 102614

MANUFACTURER'S COUPON

DO NOT DOUBLE

EXPIRES 5/31/01

**\$1.50
off**

any size box of
Breathe Right®
nasal strips



102026



5 57145 51078 4 (8100) 7 10202

**Breathe Right
Right Now.™**

PO BOX 1985
South Hackensack, NJ 07606-9867
phone [800] 858-6673
www.breatheright.com

CONSUMER: Limit one coupon per purchase as specified on the face of this coupon. No other coupon may be used in conjunction with this coupon.
RETAILER: You are authorized to act as our agent and redeem this coupon at face value plus 8 cents handling, in accordance with our redemption policy, copies available upon request. Void if copied and where prohibited, licensed and regulated. Good only in U.S.A. Cash value 1/100 cent. Send properly redeemed coupons to: CNS, Inc. P.O. Box 880288, El Paso, TX 88588-0288.